

Comment Response Summary for the Draft Final Butte Priority Soils Operable Unit Public Health Study, Phase 1

Conduct of the Butte Priority Soils Operable Unit Public Health Study, Phase 1, (hereafter, “the Butte health study”) included a release of a draft final report for public review and comment. The draft final report was released by EPA on February 28, 2014 commencing a 60-day public comment period that ended on April 29, 2014. Additionally, during a public meeting held at the Mining City Center’s Copper Auditorium on April 9, 2014, study investigators and collaborators provided more information about the study and were available to answer questions from community members. Questions posed by community members attending the public meeting were responded to by the study representatives during the “Question and Answer” portion of the meeting or during one-on-one interactions with the study representatives during the “Open House” portion of the meeting. Comment cards were also made available during the meeting for those wishing to submit comments in writing.

A total of four individuals submitted written comments on the (“draft final report”) in relation to the Butte health study public comment period. One of these commenters submitted suggestions for edits to the draft final report. Another commenter submitted two comment sets, each with unique questions to be addressed. The third commenter submitted a single comment on a comment card at the April 9, 2014 public meeting. The final commenter submitted a total of 19 separate sets of comments; however, many of the same comments or comment themes were repeated throughout the submittals.

To ensure responses to individual commenter’s comments are easily located, comment responses provided below are grouped by individual commenter. Original comment submittals are provided as Attachment 1 to this response summary. Names of each commenter have been omitted from this summary and Attachment 1.

Commenter 1: This commenter submitted comments via an email that suggested the following revisions to the Public Health Statement included at the beginning of the draft final report:

1. “After the first three bullets, consider a concluding statement like, ‘The understanding gained is applied toward making recommendations for improving the RMAP program.’”

Response: Suggested revision has been made.

2. “Your second header, ‘Blood lead levels provide...’ is not addressed by the text. That is, you don’t explain why blood lead is a good indicator of exposure. Also, too, the goals and standards are brought in rather late in the summary, and could be brought into a new paragraph here that addresses the header. I would add that there is no known beneficial effect of exposure, that the goal is no exposure but that there are standards (5 for CDC, 10 for EPA). The text is good, but maybe needs a different header.”

Response: To better represent the content presented in that section, the header has been revised to: “The Study Focus on Blood Lead Ensures Consideration of All Sources of Lead Exposure in Butte, including Superfund-related Sources.”

3. “Third header, revise to: ‘...Levels in Butte Have Declined...’”

Response: Suggested revision has been made.

4. “Page iii, second full paragraph, last sentence. Edit to: ‘...cannot be identified conclusively proven based on this analysis...reductions in other lead exposures achieved through other government programs.’”

Response: The sentence has been revised to: “The specific factors causing the higher rate of decline in Butte cannot be conclusively proven based on this analysis, but the factors could include ongoing RMAP response efforts and reductions in other lead exposure sources.”

5. “Header on page iv, revise to: ‘The RMAP ~~has been~~ continues to be and important...’”

Response: The phrase has been changed to “The RMAP continues to be an important...”

Commenter 2: This commenter submitted two sets of comments via email. Comments sought information about a variety of concerns in Butte, including:

1. “I could not look at all of the references, so excuse me if this was answered. What are the other concerns that will degrade (have degraded) the health of citizens? Lead seems to be the focus of the report. What about arsenic, mercury and other metals in the environment? Is asbestos an issue? Specifically, lead paint is unrelated to mining. What are mining related issues and how well do we understand them? And attempt to control them?”

Response: The commenter’s questions align well with information presented in section 2 of the EPA-approved work plan for the Butte health study, which details the study basis and design, including a summary of broader concerns raised by the public during scoping for the Butte health study, how those have or are being addressed. The approved work plan is available at:

<http://www2.epa.gov/region8/butte-priority-soils-operable-unit-public-health-study-remedial-design-work-plan-phase-1>

2. “Were I to reside here for 30 years, living a healthy lifestyle, am I at increased risk to certain diseases that are environmentally related? COPD? Cancer? Mercury poisoning???? If the answer is unknown, what measures are underway to learn it?”

Response: Your question is not easily answered as many diseases are associated with multiple risk factors. Susceptibility to diseases also varies across different individuals. What we can tell you is that only a limited number of properties with elevated mercury levels have been identified in the Butte area, and those have been remediated. Also, as described in the draft final health study report, a study of cancer incidence and mortality conducted by the Montana Department of Public Health and Human Services (MDPHHS) included consideration of the most common cancers, as well as cancers associated with exposure to metals present in Butte. The MDPHHS study provided an update to and expansion of a 2001 ATSDR review of Silver Bow County cancer incidence rates compared to similar data for Montana and the U.S. (ATSDR 2002). The 2002 ATSDR analysis focused on cancer outcomes associated with

exposure to heavy metals including arsenic, and, to a lesser extent, lead and mercury. Original copies of both studies are included as Appendix A to the draft final report. Based on its 2001 review, ATSDR (2002) concluded:

The data indicate a slightly elevated incidence of skin cancer in Silver Bow County when compared with age-standardized rates at the State and national level. No other cancer outcomes were consistently elevated when compared with these two reference groups. The slight increase in skin cancer incidence cannot be directly attributed to soil arsenic contamination in the area since no exposure assessments were included in this analysis.

The more recent MDPHHS study (2012) reported that the incidence of cancer for all sites (i.e., not a specific cancer site, e.g., lung) was the same among residents of Silver Bow County compared to the residents of the state of Montana and that both were the same or lower than the all sites cancer incidence for the U.S. over three time periods spanning from 1981 to 2010. For mortality due to cancer (all sites), the rate for Silver Bow County was the same for the rest of Montana for 1981-1990 and 2001-2010, but the county rate was slightly higher for the 1991-2000 timeframe evaluated. Further, MDPHHS reported:

The most common types of cancer in Silver Bow County are also the most common in Montana and in the United States. None of these cancers (except for lung cancer) are known to be affected by the heavy metals or chemicals of concern in Silver Bow County. Lung cancer is also associated with arsenic exposure. However the majority of lung cancer cases are caused by cigarette smoking (87% of cases among men and 74% of cases among women)....

Prostate is the most diagnosed cancer in Montana and in the US. The incidence of prostate cancer among residents of Silver Bow County was the same as Montana and the United States for the time intervals 1981-1990 and 1991-2000... From 2001-2010, the incidence rate in Silver Bow County was lower than Montana...

The incidence of female breast cancer among residents of Silver Bow County was lower than Montana and the United States for the time periods 1981-1990 and 1991-2000 ... From 2001-2010, the incidence rate in Silver Bow County was the same as Montana and the United States...

The incidence of colorectal cancer among residents of Silver Bow County was the same as Montana and the United States for all three time intervals...

The incidence of lung & bronchus cancer was the same among residents of Silver Bow County and Montana for all three time intervals...

According to MDPHHS, the best way to assess the effects of environmental exposure on cancer risk in humans is to measure cancer incidence. Cancer incidence measures the number of newly diagnosed cancer cases in a population each year. Cancer mortality, on the other hand, is the number of deaths that occur each year from cancer. Mortality reflects both the risk of getting cancer and the ability to get effective diagnosis and medical treatment. Two communities can have similar incidence rates, but very different mortality rates. In fact, a community can have a relatively low incidence rate, but a relatively high mortality rate because of limited access to services. Therefore, incidence rates are the best way to compare the risk of getting a disease and mortality rates are a way to compare access to care and treatment after people become ill.

3. “What approaches and attitudes are present among the business leaders, technologists and citizens that would tend to prevent the [pollution] and cleanup that the area faces from a history of, what I must assume, was irresponsible mining practices? Note, I am aware that much particulate [pollution] of the air is caused by coal and wood burning in homes during winter, and forest fires in the summer. Please feel free to criticize my causal assumption. Hindsight is always clearer.”

Response: This comment is really focused on questions that are beyond the scope of the Butte health study. We suggest the commenter contact Nikia Greene at EPA or Dan Powers at BSB Health Department to further explore the commenter’s question.

4. “has the level of lead decreased in the environment over the same time period as measured in public and private spaces. Clearly the blood levels show a decrease, but do they indicate its decrease in the environment? Blood levels are one measure, but let's add other measures. True, the presence of Pb in blood indicates its presence in the environment of those individuals. I suggest that all city parks and playgrounds be tested for metals at least annually, if not twice a year. If these tests have been done, please report them. Is there a test that can be applied to biological samples. For example, tree rings should contain a history of both water and air contaminants. Old and young trees are cut down [every] year. It would seem that tests by area of the city might be informative. I suggest that vegetables and fruits that are grown for consumption should be tested as well. If nothing else, a sample of produce from the public gardens adjacent to the Hummingbird restaurant should be tested annually. I am unfamiliar whether other potential test sites of this nature exist. It is conceivable that a controlled test garden(s) within the area could be created and maintained by some entity. Another testing location would be the soil on selected trails, abandoned and converted railroad beds and otherwise in all directions of Butte.”

Response: Blood lead is a biomarker of exposure to lead that an individual may contact in their environment, which would include both public and private spaces, and from products they use and food they consume. Blood lead measurements do not distinguish how much individual sources of lead exposure contribute to the overall exposure. Using the available blood lead data to assess exposures in Butte is desirable because blood lead levels provides a direct and relatively stable measure of all sources of lead exposures a child may have, including lead exposures from soil, dust, water, air, food, paint, and

consumer products. A decline in blood lead levels for the Butte health study population over time is consistent with extensive programs to reduce sources of lead exposures, including remediation of mine sources, as well as other sources common to all communities. There are thousands of samples of soil from around Butte that document lead concentrations in soil around Butte. Lead does not typically accumulate in plants, so there is not a need to monitor trees or other plants.

5. “Is there no way of attributing the presence of Pb (and other metals) to mining operations as opposed to the other cited Pb sources? The results of the above paragraph's testing may provide a hint to this.”

Response: All communities have multiple sources that contribute to lead exposures. In addition to lead-based paint and socio-economic risk factors potentially influencing blood lead levels in Butte, the draft final report also notes proximity to past and ongoing mining areas as a potential contributor to differences in blood lead levels between different areas of Butte (i.e., Uptown and the Flats). However, as noted in response to the prior comment, blood lead measurements do not distinguish how much individual sources of lead exposure contribute to the overall exposure.

6. “Having submitted these suggestions, I still commend all who worked on the existing study for a job well done. As always, studies beget studies.”

Response: Comment acknowledged.

Commenter 3: This anonymous comment was received on an index card submitted at April 9, 2014 public meeting.

1. “Why isn’t the public more involved with the Citizens Technical Env. Committee CTEC should involve the public. (For the people?!?)”

Response: This comment has been referred to CTEC.

Commenter 4: This commenter submitted 19 separate sets of comments via email, totaling 90 pages of comments. To guide review of the comment responses, please note the following:

- Comments within and among the different submittals often repeated comment themes, many of which had been raised during the public comment period for the Butte health study work plan and were already addressed in the response to comment summary for that work plan. In such cases, responses summarized below refer the commenter to prior responses. Similar comments are considered together in development of a single response to each theme for simplicity.
- A number of comments received were presented as lists of topics or phrases without clear linkages to the draft final report, the Butte health study methodology, or its findings. Comments lacking relevance to the study are noted as such in responses below.
- Many comments lacked sufficient information or context that would allow for a response without inference. If it was necessary to infer what the commenter might have meant by a specific comment, that comment was not addressed in this response summary.

Commenter #4 Comment Response Summary

1. BPSOU Action Levels – In 7 of 19 comment submittals, the commenter expressed concerns regarding the adequacy of BPSOU remedy and the need for updating the soil lead action level for consistency with CDC’s blood lead reference value, 5 micrograms per deciliter. The commenter asserted that the prior BPSOU risk assessments were flawed, that BPSOU action levels are not protective of human health, and that the action levels ignore environmental justice. The commenter requested confirmation that properties addressed by RMAP were considered safe for residents.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 1.B.1, 1.B.2, and 1.B.3 presented in Table 1 and comments 2.A.2, 2.C.4, 2.C.5, 2.C.9, 2.D.1, 2.E.12, 2.E.13, 2.F.9, 2.F.14, 2.G.1, and 2.G.2 of Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013. Once a property has been addressed by RMAP, it is considered safe for families who reside there. In addition to cleanup of soils where action levels are exceeded, as part of the residential access agreement covenants, the program includes provisions for future development and maintenance of addressed properties to ensure long-term integrity of the work completed. As part of the RMAP cleanup process, measures are also taken to ensure underlying soils that may exceed action levels are indicated with visual markers prior to backfilling excavated soils at the surface.

2. Public Involvement – In 10 of 19 comment submittals, the commenter asserted that the health study process has failed to include meaningful public involvement.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.B.1 through 2.B.12 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

3. Environmental Justice – In 12 of 19 comment submittals, the commenter requested that EPA comply with environmental justice commitments. The commenter asserted that health study ignores environmental justice concerns with regard to the study involvement process and study design. Commenter asserts that risk assessments conducted for the study area also did not address environmental justice concerns and that the proposed plan and preferred alternative for BPSOU are null and void as a result.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.C.1 through 2.C.14 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit

Public Health Study Remedial Design Work Plan, dated May 2013. In addition, please see response to Comment #1 above regarding the adequacy of BPSOU action levels and prior studies.

We disagree with the commenter's assertions that the health study has ignored the environmental justice concerns of low-income citizens in Butte. The Butte study population blood lead data were compiled from county blood lead records including those from Butte's Women, Infants, and Children (WIC) program clients as well as from individuals referred via the RMAP and local physicians. The majority of the blood lead records came from patients recruited for regular blood lead testing through WIC. The qualification for WIC is 175% of the federal poverty level or below. In addition, census data for Butte indicates that the locations in Butte where the study population resided at the time of blood lead testing corresponded to areas with the highest percentages of households living below the poverty level. Thus, relative to the broader Butte population, the Butte study population is expected to represent Butte's low-income citizens who are likely at higher risk for blood lead exposure. While it is most appropriate to focus the study on this portion of the Butte population that is at greatest risk for lead exposure, it is recognized that doing so reduces the generalizability of the Butte health study findings to the portions of the Butte population that are at lower risk for lead exposure based on socioeconomic factors.

We note also the lack of relevance for the commenter's assertions that Butte health study has failed to consider the health effects and disease outcomes of lead exposure on low-income citizens. As detailed in response to Comment # 9 below, the purpose of the study is not to evaluate health/disease outcomes; this applies to the general Butte population as well as specific subpopulations (e.g., low-income citizens).

4. Peer Review – In 9 of 19 comment submittals, the commenter requested independent peer review of the health study prior to finalization. The commenter asserted that EPA has reneged on promise of an independent peer review. Comments assert that methodological issues identified by the commenter support the need for independent peer review. Comments assert that journal publications will not satisfy need for independent peer review.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.D.1 through 2.D.10 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

5. Precautionary Principle – The commenter asserted that the Precautionary Principle needs to be incorporated into the health study.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.H.1 and 2.H.2 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

6. Bioavailability – The commenter questioned whether the health study should look at hair and nail samples to determine the bioavailability of chemicals of concern and asked why bioavailability data has not been correlated with chemical concentrations in attics and yards. This commenter asserted that the lead and arsenic found in homes is more bioavailable than in tailings dust.

Comment Response: The commenter appears to confuse biomonitoring with bioavailability in these comments. The bioavailability of lead in Butte soils was measured in several different animal studies and found to be very low. The bioavailability of lead in Butte dust was not measured; therefore, the default value in EPA's IEUBK model of 30% was used to be conservative. With regard to biomonitoring for lead, the U.S. Centers for Disease Control and Prevention (CDC 2013) states: "Blood lead measurement is the preferred method of evaluating lead exposure and its human health effects." A comment submitted during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan also asserted that hair and fingernail sampling for arsenic should be part of the study as these give a better picture of chronic exposures in Butte. A response to this comment was provided in the final approved work plan. Please see response to comment 2.G.8 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

7. Synergistic and Cumulative Effects – In 4 of 19 comment submittals, the commenter asserted that the health study fails to consider synergistic and cumulative effects of exposure to toxics in Butte, which is a shortcoming of the study.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.C.8, 2.C.13, 2.G.2, and 2.G.7 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

8. Incidence and Mortality Studies – In 7 of 19 comment submittals, the commenter asserted that other recent studies in Butte have found that disease rates for chemicals of concern in Butte are steady or increasing and that the health study should look at disease incidence and mortality instead of exposure data.

Comment Response: We disagree with the commenter's assertion regarding the findings of recent studies of disease rates in Butte and the preference for health outcome data versus exposure data in Butte. The commenter is referred to response to Comment #2 for Commenter 2 above regarding the findings of recent mortality and incidence studies in Butte. Regarding the preference for health outcome data versus exposure data in Butte, similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.F.1 through 2.F.21 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

9. Study Purpose – The commenter asked: “What exactly, in as succinct a statement as possible, is the purpose of Phase 1 of the Health Study?”

Comment Response: The purpose of the Butte health study is described on pages ii, xv, and 1 of the February 2014 Draft Final Report. For clarity, the purpose is also summarized below.

The purpose of the study is to evaluate the effectiveness of ongoing remediation and residential metals abatement efforts in the study area that have occurred since the early 1990s and to identify areas of potential improvements to current remediation/abatement approaches based on that evaluation. Toward that end, the EPA-approved study design focuses on assessing lead exposures represented by several years (2003 through 2011) of available blood lead data collected from Butte children.

Specifically, this study employs a descriptive cross-sectional analysis of blood lead data and other factors that may influence blood lead levels in children to characterize the following:

- how Butte blood lead levels represented in the available data have changed over this time period,
- how blood lead levels in the Butte study population compare to blood lead levels for a demographically-similar reference dataset that does not have Butte’s Superfund history, and
- what factors in Butte might be contributing to differences in blood lead levels across the Butte study population and between Butte study population and the reference blood lead dataset.

Other available RMAP data for the same study period are considered in the study, secondary to the primary analyses of blood lead data. Recommendations are included regarding potential improvements to current remediation/abatement approaches that may be indicated based on interpretation of the results from these analyses.

To further assure clarity regarding the study purpose, we also note that the purpose of this study was not to address questions of causality or to evaluate health outcomes associated with the blood lead levels characterized for the Butte study population. Numerous “methodological problems” asserted by this commenter relate to causation and/or health/disease outcome studies. These comments, therefore, are not relevant to this study and are not addressed in this response to comment document.

10. Study Focus on Lead – In 4 of 19 comment submittals, the commenter questioned the focus of the study on lead and/or asserted the need for consideration of other toxics in Butte.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.G.1 through 2.G.8 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

11. Availability of Raw Study Data – In 3 of 19 comment submittals, the commenter requests that the raw data used in the study be made available to the public for verification of study findings.

Comment Response: The raw data used in the Butte health study includes personally identifying information about individuals whose blood lead records were used in the study. Such information is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security and Breach Notification Rules and cannot be released to the public. Requests for de-identified data used in the study (or other existing biomonitoring data) would have to be reviewed and approved by the Butte Silver Bow County Health Department. Support for such requests would include why the data are requested and a protocol for how data would be used and protected. Due to the HIPAA Privacy Rules, verification of the de-identified records against the raw data would not be possible; however, the commenter is assured that each piece of information from the raw data that was compiled from original paper records into an electronic database was checked by a second team member to assure accurate transfer of the original data.

12. Scope of Future Studies – The commenter asked what the scope of future studies will be and whether these will include medical monitoring of chronic exposure to all toxics of concern in Butte.

Comment Response: Similar comments were submitted by the commenter during the public comment period for the Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan. Responses were provided in the final approved work plan. Please see responses to comments 2.A.1, 2.A.2, 2.A.4, 2.A.12, 2.B.3, 2.B.4, 2.F.1, 2.F.2, 2.F.3, and 2.G.8 presented in Table 2 of Attachment 3 to the approved Butte Priority Soils Operable Unit Public Health Study Remedial Design Work Plan, dated May 2013.

13. Focus on Acute vs. Chronic Exposures – In 2 of 19 comment submittals, the commenter asserted that the study focuses on acute exposures when focus on chronic exposures is needed.

Comment Response: The Butte health study focuses on blood lead data as a biomarker for exposure. According to the CDC, blood lead data “reflect both recent intake and equilibration with stored lead in other tissues, particularly in the skeleton” (http://www.cdc.gov/biomonitoring/Lead_BiomonitoringSummary.html). Further, by including hundreds of blood lead samples collected over a nine year period, the Butte health study presents a long term view of ongoing lead exposures in Butte. The Butte health study does not seek to identify sources of lead exposure contributing to the blood lead result for a given individual within the study population or to identify whether such sources might have been contacted by the individual over a short (i.e., acute) or long (i.e., chronic) period of time. Such endeavors are not necessary to address the study objectives.

14. Prediction Intervals and Confidence Intervals – The commenter asserted the following as a methodological concern with the Butte health study: “Using confidence intervals when prediction intervals are warranted.” The commenter also asked: “On what bases were the confidence and prediction intervals determined?” This commenter also questioned how the Butte health study avoided problems with failure to quantify the degree of precision or imprecision in confidence intervals.

Comment Response: The commenter appears to be confused. Prediction intervals are the estimate of the interval in which the future observations will fall. For this study we were attempting to estimate the population mean of the current and past populations, so confidence intervals are the appropriate metric to use. While prediction intervals were not used, all confidence intervals given in the report have been defined as to their precisions (e.g. 95% confidence interval of a geometric mean).

15. Regression on Residuals – The commenter asserted the following as a methodological concern with the Butte health study: “Problems with regression on residuals.”

Comment Response: Residuals were used only to determine normality as for the regression analysis, the error terms should be normally distributed.

16. Representativeness of Study Population – The commenter asserted the following as a methodological concern with the Butte health study: “Failure to show the representative nature of the population sampled in Butte.”

Comment Response: The sampled population is not representative of Butte as a whole since the samples came mainly from the Women, Infants, and Child (WIC) population. The WIC-based sample population over-represents individuals within the population who fall within lower income levels, which historically has corresponded to over-prediction of the average blood lead levels for the general population.

17. Variable Selection Methods – The commenter asserted the following as a methodological concern with the Butte health study: “Assuming linearity is preserved when variables are dropped. One common mistake in using ‘variable selection’ methods is to assume that if one or more variables are dropped, then the appropriate model using the remaining variables can be obtained simply by deleting the dropped variables from the “full model” (i.e., the model with all the explanatory variables). This assumption is in general false. Cook and Weisberg (1999) Applied Regression Including Computing and Graphics, Wiley.”

Comment Response: The commenter appears to be confused. No statistical selection method (stepwise, forward or backward) was used. Each variable was tested separately and then together for use in the models.

18. Regression Model Use – The commenter asserted the following as a methodological concern with the Butte health study: “Using a regression model without knowing the subject.”

Comment Response: The commenter appears to be confused. The subject is known. Linear regression is used in the study to determine a mean blood lead level after adjusting for race, poverty index level and housing age.

19. Problems with Stepwise Model Selection Procedures – The commenter asserted the following as a methodological concern with the Butte health study: “Problems with Stepwise Model Selection Procedures ‘... perhaps the most serious source of error lies in letting statistical procedures make decisions for you.’ ‘Don’t be too quick to turn on the computer. Bypassing the

brain to compute by reflex is a sure recipe for disaster.’ Good and Hardin, Common Errors in Statistics (and How to Avoid Them), p. 3, p. 152.”

Comment Response: The commenter appears to be confused. Stepwise model selection (a statistical selection method) was not used in the analyses on these data.

20. Common Mistakes in Multiple Regression– The commenter noted five points under the heading, “Common Mistakes in Multiple Regression Avoided in the Health Study?”

Comment Response: The commenter’s points are unclear as to what, if any, relevance they have to specific methods used in Butte health the study. However, with regard to study methods, we note: 1) that residuals were tested for normality; 2) outliers were looked for, but because we had no reason to assume that any outliers were not part of the overall population, they were not removed; 3) plots were examined for fit; 4) stepwise regression was not used in this study; and 5) errors were not confused with residuals.

21. Estimating vs. Predicting– The commenter asserted the following as a methodological concern with the Butte health study: “Confusing ‘estimating’ with ‘predicting’.”

Comment Response: Predicting refers to something that has yet to occur. In this study, population means are estimated based on a sample from that population.

22. Consideration of Prior Studies– The commenter asked the following with regard to methodological concerns with the Butte health study: “How were prior studies used to determine which variables to include in the modes and study?” The same commenter also asked: “What role did prior studies of exposure, disease rates and mortality rates play on the development of the first phase of the Butte Health Study? What was superior about the methodology used in Phase I of the Butte Health Study as compared to the methodology used in other studies of exposure, disease rates/incidences and mortality? Why should we have more confidence in the methodology used in this study as compared to the methodology used in previous studies related to the health effects of the toxics of concern in Butte?”

Comment Response: Based on numerous publications, we know that certain demographic characteristics can be predictive of blood lead levels. These were the variables explored in the Butte health study for correlations to the measured blood lead levels in NHANES and in Butte. Prior studies of exposure, incidence and mortality were described in the study work plan and in the draft final report. The commenter is also referred to response to Comment #8 in this response summary and response to Comment #2 for Commenter 2 above. The Butte health study is not an incidence or health outcome study, thus, comparison of its methodology with such studies is not appropriate.

23. Bias– The commenter asserts that the Butte health study is or may be subject to several types of bias that should be addressed.

Comment Response: The commenter’s assertions that Berkson’s bias and collider bias are issues with the Butte health study are not well-founded as neither of these types of bias are relevant to the study

methodology. Similarly, the commenter asserts that the study fails to adequately deal with 18 different biases the commenter lists. Of these, only two (informational and selection bias) are of potential relevance to the study. Bias in an epidemiological study can broadly be categorized as either information or selection bias. Information bias is the term used to define the potential error introduced into a study when the outcome/ dependent variable (here, BLL levels) or independent variables/covariates (year, house age, season, etc.) for study subjects are misclassified. In the Butte Health Study, concerns about information bias are minimal. The majority of the variables used including year of BLL test, season of BLL test, age of the child at the time of the test, and gender of the child are unlikely to have been recalled or reported incorrectly in the WIC client records from which the information was obtained. Neighborhood was not self-reported, but mapped to a census tract by the researchers using the child's address. House age was also not self-reported, but obtained from land survey and property tax databases using property addresses reported in WIC client records. Additionally, house age information was missing for approximately 35% of children (945/2724), but rather than dropping these children, they were included in the analysis with a missing house age category. BLL measurements for all children in the study were obtained by the capillary method using the same procedure and technique alleviating concerns that changes or differences across groups in how the samples were collected or analyzed explain any of the results.

Selection bias, the second broad category of bias, occurs when systematic differences exist between individuals selected into the study and individuals not selected into the study. The Butte Health Study used blood lead records collected by the Butte Silver Bow Health Department as part of the RMAP and WIC programs. The specific years of data, 2003 to 2010, and specific age ranges, 12 to 60 months, selected for evaluation in the study were carefully considered as detailed in section 2 of the draft final report. The intent of the study was to examine the relationship between several factors (year, neighborhood, house age, child's age, sex, season) and blood lead levels and we have no reason to suspect that the way these records were collected or selected for use in this study would have led to a distortion of the relationships between these factors and BLLs. Importantly, though, the use of this data source, in which the majority of the children were WIC participants and for which census data for Butte indicates that the locations in Butte where the study population resided at the time of blood lead testing corresponded to areas with the highest percentages of households living below the poverty level, may limit the generalizability of these findings to the entire Butte population. The generalizability of a study refers to the populations to which it is appropriate to apply the study's findings. The Butte Health Study provides important insight into the blood lead levels of children living in Butte, but it should be noted that the study population is likely drawn from a population of lower socioeconomic status than the Butte population in general and, because lower socioeconomic status correlates with higher blood lead concentrations, the concentrations may not be representative of Butte children overall. The commenter is also referred to responses to Comment #3 and #27 for additional discussion of the generalizability of the Butte study population to the overall population of Butte.

24. Confounding– The commenter questions how the Butte health study methodology addresses/eliminates confounding problems related to interpretation of the etiology of cases.

Comment Response: Confounding problems related to interpretation of the etiology or cause of cases are not relevant to this study. As noted in response to Comment #9, the purpose of this study was not to address questions of causality or to evaluate health outcomes associated with the blood lead levels characterized for the Butte study population. With respect to the study methodology, adjusting the models for age, sex, season, etc. was conducted to avoid potential confounding of model results due to these variables. These and other potential factors that might influence interpretation of study results are discussed in the draft final report.

25. Laboratory Quality – The commenter expresses concern about false-negative sampling errors with capillary blood lead sampling and asks: “What assurance does the public have that labs that do the sampling and analysis are certified and reliable?”

Comment Response: The analytical laboratory that performed the analysis of blood lead samples represented in the Butte dataset holds all required certificates and licenses, and successfully participates in required proficiency testing programs (see <http://tamaracmedical.com/>). As described in the draft final report, a key concern with the use of finger stick sample collection is the potential for external contamination of the blood sample from lead on the skin which is very difficult to remove completely (ACCLPP 2012). Such external contamination could result in a rate of higher false positives or otherwise bias Butte sample results high compared to NHANES sample results. However, correlation coefficients between capillary and venous methods have been reported to range from 0.96-0.98 in paired testing (Schlenker et al. 1994) and Butte WIC sample collection methods include preparation of the skin location using laboratory-provided wipes that are designed to reduce the potential for external lead contamination. The laboratory used for the Butte blood lead data reports: “The correlation between paired, simultaneously drawn extraction method filter paper and venous samples is >.970. Additionally, undetected-elevated and falsely-elevated rates may be considered clinically insignificant. These findings are documented by three published, peer-reviewed studies involving 363 paired, simultaneously drawn extraction method filter paper and venous sample comparisons.” (Yee et al. 1995; Srivuthana et al. 1996; and Yee 1997)

26. Failure to Reduce Random Variation – The commenter asks how the study addresses problems with failure to reduce random variation.

Comment Response: Random variation in a population is not something we can avoid nor should try to reduce when doing this type of study. The confidence intervals estimated take the variance in the population into consideration.

27. Conceptual Framework Problems – The commenter asserts that four “conceptual framework problems” including failure to adequately characterize the external population, the target population, and the Butte health study population.

Comment Response: Characterization of the Butte study population and the reference population, NHANES, is provided in the draft final report, with additional detail in the EPA approved Technical Memorandum – Proposed Reference Blood Lead Data for Use in the Butte Health Study, which is included as Appendix D to the draft final report. For the Butte study population, county blood lead

records include those from Butte’s Women, Infants, and Children (WIC) program clients as well as from individuals referred via the RMAP and local physicians. The majority of the blood lead records came from patients recruited for regular blood lead testing through WIC. The qualification for WIC is 175% of the federal poverty level or below. In addition, census data for Butte indicates that the locations in Butte where the study population resided at the time of blood lead testing corresponded to areas with the highest percentages of households living below the poverty level. Thus, relative to the broader Butte population, the Butte study population is likely at higher risk for blood lead exposure due. While it is most appropriate to focus the study on the portion of the Butte population that is at greatest risk for lead exposure, doing so reduces the generalizability of the study findings to the portions of the Butte population that are at lower risk for lead exposure based on socioeconomic factors.

28. Case/Control Study Issues – The commenter asserts that the Butte health study methodology suffers from issues related to overmatching and selection of controls, assessment of reliability problems, assessment of validity problems, and misclassification problems. A reference cited quoted pertains to overmatching in studies relating exposure and disease. In a later comment, the commenter also notes: “Failure to do any case-control studies.”

Comment Response: Comments pertaining to case/control studies are not applicable to the health study which is not a case/control study and does not evaluate the relationship between exposure and disease. Further, considering the study research questions and available data, case-control study designs/approaches would not be appropriate.

29. Causality Methodology Problems – The commenter asserts that the Butte health study methodology suffers from “serious causality methodology problems that are visible in the Study” and need to be addressed.

Comment Response: Comments pertaining to causality studies are not applicable to the Butte health study which does not evaluate causation. The study was descriptive by design and there are no causal inferences to be made. This study can only look at statistical correlations between certain factors (age, sex, house age, neighborhood), but no conclusions are drawn about “causation.” This methodology is appropriate for a study in which blood lead levels are the response and where other variables are evaluated as predictors of blood lead levels among the study group. Even if the study were evaluating an etiological hypothesis, causal inferences cannot be made based on a single study. The Hill criteria cited by the commenter are considered across a body of epidemiological literature to evaluate evidence for making causal inferences. The Hill criteria are not applicable to the Butte health study methodology.

30. Blood Lead Instrumentation/Detection Levels – The commenter asserts: “The issue of whether or not the instrumentation/detection level used in analyzing the blood lead data is adequate needs to be addressed. Is the current detection level set at too high a bar? Do the current detection limits used in Butte adequately address whether or not adverse health effects are occurring in Butte children?”

Comment Response: Consideration of blood lead instrumentation and detection limits was a key part of the data refinement process used to develop the blood lead database used in the Butte health study.

During the study data collection timeframe (2003 through 2010), blood lead samples had been submitted for laboratory analysis with a detection limit of 1 µg/dL, which is sufficiently sensitive for evaluation of the distribution of blood lead levels in a population relative to the CDC blood lead level of concern (10 µg/dL) that was applicable from 2003 through 2010, as well as the current CDC blood lead reference value (5 µg/dL). As noted in the draft final report, in December 2011, the BSB Health Department began using a portable lead analyzer, LeadCare II, with a detection limit of 3.3 µg/dL. Use of the LeadCare II analyzer was initiated to allow for more immediate follow-up when blood lead results are elevated. However, for the purposes of this study, it was determined that records obtained by use of the LeadCare II device lack sufficient sensitivity and precision to support the study objectives and could not be used. This is why the study excludes LeadCare II data from analyses of the 2011 data in comparison to the 2003 through 2010 data. Recommendations made in the draft final report include BSB's continued adoption of the CDC recommendations for confirming screening blood lead test results by venous sampling if greater than 5 µg/dL and update the screening value used when/if the CDC reference value is updated in the future. Recommendations also include re-initiating blood lead testing procedures that produce reliable screening results at a detection limit of 1 µg/dL or lower given that blood lead levels in Butte are now low enough that trends in blood lead levels cannot be discerned using testing procedures with higher detection limits (e.g., the LeadCare II analyzer). The ability to characterize the trends is needed to continue to track the effectiveness of the RMAP.

With regard to the above, it is important to clarify that blood lead data used in the health study represent a biomarker of exposure, not health effects. Therefore, the commenter's question about whether or not the current detection limits used in Butte adequately address the occurrence of adverse health effects is not relevant to this study. That said, the BSB Health Department confirms via venous sampling and laboratory analysis all LeadCare II screening results if equal to or greater than 5 µg/dL, thus accelerating the timeframe for follow-up of cases with suspected elevations of blood lead and providing a more precise and sensitive measure of blood lead for that individual.

31. Long Latent Periods – The commenter asserts the Butte health study methodology fails to “deal with the problem of long latent periods.”

Comment Response: This comment is not relevant to the health study; long latency periods are not a subject of this study.

32. Lack of Covariate Data – The commenter asserts a “lack of covariate data.”

Comment Response: Several covariates are included in the Butte health study models as detailed in the draft final report.

33. Rare Outcome Events – The commenter asserts: “Methodology not suited to rare outcome events in non-clinical populations.”

Comment Response: There are no rare outcomes associated with the Butte health study population.

34. Cross-Sectional Studies – The commenter asserts the Butte health study fails to do any cross-sectional studies.

Comment Response: The commenter appears to be confused. The study is cross-sectional in nature.

35. Genetic, Space-Time Cluster, and Time Trend Studies – The commenter asserts the Butte health study fails to do any genetic studies, space-time cluster studies, and time trend studies.

Comment Response: Considering the study research questions and available data, such study designs/approaches would not be appropriate.

36. Ecologic Inference Making – The commenter asserts: “Poor ecologic inference making.”

Comment Response: Ecologic inference making is not relevant to the Butte health study approach.

37. Gene-Environment Interaction – The commenter asserts: “Poor consideration of gene-environment interaction.”

Comment Response: Considering the Butte health study research questions and available data, such consideration would not be appropriate.

38. Bayesian Modeling – The commenter asserts: “Phase I suffers from the failure to do Bayesian modeling.”

Comment Response: Bayesian modeling was not necessary to address the Butte health study research questions.

39. Population Randomization – The commenter asserts: “Given that there is no randomization in the populations studied imbalances in the characteristics of those exposed can occur.”

Comment Response: This would not have been an appropriate way to address the Butte health study research questions. Also, randomizing lead exposure would be unethical.

40. Cohort Studies – The commenter asserts methodology issues related to cohort studies.

Comment Response: These comments are not relevant to the Butte health study, which is not a cohort study.